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XYPHOS BIOSCIENCES, INC.

**UNITED STATES DISTRICT COURT**  
**NORTHERN DISTRICT OF CALIFORNIA**

VIKASH BHAGWANDIN, an individual;

Plaintiff,

v.

XYPHOS BIOSCIENCES, INC., a Delaware  
corporation; and DOES 1 through 50,  
inclusive;

Defendants.

Case No.

**DEFENDANT XYPHOS BIOSCIENCES,  
INC.'S NOTICE OF REMOVAL TO THE  
UNITED STATES DISTRICT COURT FOR  
THE NORTHERN DISTRICT OF  
CALIFORNIA PURSUANT TO  
28 U.S.C. §§ 1331, 1441, AND 1446**

TO THE CLERK OF THE UNITED STATES DISTRICT COURT, NORTHERN DISTRICT OF CALIFORNIA, PLAINTIFF VIKASH BHAGWANDIN, AND HIS ATTORNEY OF RECORD:

PLEASE TAKE NOTICE THAT, Defendant XYPHOS BIOSCIENCES, INC. (“Xyphos”) by and through undersigned counsel, hereby removes this action from the Superior Court of the State of California for the County of San Mateo (“State Court”) to the United States District Court for the Northern District of California pursuant to 28 U.S.C. §§ 1331, 1441, and 1446.

**I. THE STATE COURT ACTION**

1. On March 23, 2022, Plaintiff Vikash Bhagwandin (hereinafter “Plaintiff”), filed a Civil Complaint (the “Complaint”) in the Superior Court of the State of California, County of San Mateo, entitled *Vikash Bhagwandin, Inc. v. Xyphos Biosciences, Inc., a Delaware Corporation; and DOES 1 through 50, inclusive*, Case No. 22-CIV-01256 (“The State Action”).

2. On or about March 23, 2022, Plaintiff served a Summons, Complaint, Notice and Acknowledgement of Receipt of Summons and Complaint, and Civil Case Cover Sheet on Counsel for Xyphos – Ogletree, Deakins, Nash, Smoak & Stewart, P.C. See Declaration of Benjamin A. Mains (“Mains Decl.”) filed herewith, ¶ 2, Exh. A. The Complaint asserts claims for: (1) Retaliation in Violation of California Labor Code Section 1102.5; and (2) Wrongful Termination in Violation of Public Policy. *Id.*

3. On April 12, 2022, Plaintiff first effected service of the Summons and Complaint on Xyphos. See Mains Decl. ¶ 3, Exh. B.

4. Pursuant to 28 U.S.C. § 1446(a), true and correct copies of all process, pleadings, and orders served upon Xyphos, and all records and proceedings in the State Action are provided with this Notice of Removal. See Mains Decl. ¶¶ 2-4, Exhs. A, B.

5. In accordance with 28 U.S.C. § 1446(d), a copy of this Notice of Removal is being served upon Plaintiff and a copy is being filed with the Clerk of the Superior Court of the State of California, County of San Mateo and the Clerk of the Northern District of California. See Mains Decl. ¶¶ 2-4. True and correct copies of the Notice to the Plaintiff and the State Court shall be filed

promptly.

## **II. REMOVAL IS TIMELY**

6. A defendant in a civil action has 30 days from the date it is validly served with a summons and complaint to remove the action to federal court. 28 U.S.C. § 1446(b).

7. As set forth in Paragraphs 2 above, Plaintiff first effected service on Defendant Fastenal on April 12, 2022, pursuant to California Civil Procedure Code § 415.30. *See* Mains Decl. ¶ 3, Exh. B. Xyphos timely executed a “Notice of Acknowledgment and Receipt” of the summons and Complaint on April 12, 2022, returned it to Plaintiff’s counsel, and service on Xyphos was effective on that date. *Id.*, *see* Cal. Civ. Proc. § 415.30(c) (“Service of a summons pursuant to this section is deemed complete on the date a written acknowledgement of receipt of summons is executed, if such acknowledgment thereafter is returned to the sender.”). Xyphos is filing this Notice of Removal within 30 days of service, and removal therefore is timely pursuant to 28 U.S.C. § 1446(b)(2)(B).

## **III. JURISDICTION**

8. In accordance with 28 U.S.C. §1446(a), this Notice of Removal is filed in the District Court of the United States in which the action is pending.

9. The Superior Court of the State of California, County of San Mateo, is located within the territory of the Northern District of California. Therefore, this Court is the proper venue for this action it is in the “district and division embracing the place where such action is pending.” 28 U.S.C. § 1441(a).

## **IV. SATISFACTION OF FEDERAL RULE OF CIVIL PROCEDURE 7.1 AND CIVIL LOCAL RULE 3-15.**

10. In accordance with Federal Rule of Civil Procedure 7.1 and Civil Local Rule 3-15, Xyphos concurrently files its Corporate Disclosure Statement and Certification of Interested Parties or Persons.

## **V. GROUNDS FOR REMOVAL**

11. “The district courts shall have original jurisdiction of all civil actions arising under

the . . . laws . . . of the United States.” 8 U.S.C. § 1331. “[A]ny civil action brought in a state court of which the district courts of the United States have original jurisdiction, may be removed by the defendant . . . to the district court of United States for the district and division embracing the place where such action is pending.” 28 U.S.C. § 1441(a). Defendant bears the burden of establishing federal subject matter jurisdiction. *See Emrich v. Touche Ross & Co.*, 846 F.2d 1190, 1195 (9th Cir. 1988).

12. This action arises under the laws of the United States because the resolution of Plaintiff’s claims will necessarily and substantially depend upon a question of federal law. In his Complaint, Plaintiff asserts two causes of action, both under California state law: (1) wrongful termination in violation of public policy, and (2) whistleblower retaliation in violation of California Labor Code Section 1102.5. Complaint ¶¶ 23-39. In *Gunn v. Minton*, 568 U.S. 251, 258 (2013), the United States Supreme Court summarized the applicable test for determining federal question jurisdiction in cases such as this, when only state law causes of action have been asserted:

[F]ederal jurisdiction over a state law claim will lie if a federal issue is: (1) necessarily raised, (2) actually disputed, (3) substantial, and (4) capable of resolution in federal court without disrupting the federal-state balance approved by Congress. Where all four of these requirements are met . . . jurisdiction is proper because there is a “serious federal interest in claiming the advantages thought to be inherent in a federal forum,” which can be vindicated without disrupting Congress’s intended division of labor between state and federal courts.

*Gunn v. Minton*, 568 U.S. 251, 258 (2013) (citation omitted).

13. Here, pursuant to *Gunn*, and as expressly pleaded in Plaintiff’s Complaint, resolution of Plaintiff’s causes of action will **necessarily** and **substantially** depend upon this Court’s interpretation of the Federal Food, Drug, and Cosmetic Act (“FDCA”), specifically the requirements of Title 21 of the Code of Federal Regulations (“Title 21”), 21 C.F.R. §§ 312 and 600, and that regulation’s application to the alleged conduct here. *See* 21 C.F.R § 312.2 (regarding the applicability of these Parts to the FDCA.)

14. As pleaded in the Complaint, Plaintiff alleges that he “had a reasonable belief that the information he provided to Defendant,” in conjunction with Xyphos’ pharmacological research

concerning a particular “therapy platform,” “disclosed a violation of the Code of Federal Regulations (‘CFR’) Title 21 – Food and Drugs.” Complaint ¶¶ 15, 27. Plaintiff specifically asserts that he “reasonably believed that the information he provided to Defendant disclosed a violation of Parts 312 and 600 of Title 21. Part 312 regulates Investigational New Drug Applications and Part 600 regulates Biological Products.” *Id.* Tellingly, Plaintiff pleads no California state statutory or regulatory basis to support his claims.

15. As Plaintiff pleads *no alternative theories* in support of either his wrongful termination claim or his retaliation claim, federal question jurisdiction lies. This Court, *not the state court*, is the only qualified forum vested with the authority to interpret the FDCA and Title 21’s regulations and thereby to determine: (1) whether Plaintiff disclosed a violation of the FDCA and/or that Title; and (2) whether Plaintiff’s conduct constitutes a protected disclosure. Plaintiff’s Complaint accordingly—and unavoidably—raises *necessary* and *substantial* questions of federal law.

#### A. Necessity

16. Federal question jurisdiction only attaches when a question of federal law is a “necessary” element of the claim. *Gunn v. Minton*, 568 U.S. 251, 258 (2013). As such, if “a claim can be supported by alternative and independent theories—one of which is a state law theory and one of which is a federal law theory—federal question jurisdiction does not attach.” *Rains v. Criterion Sys., Inc.*, 80 F.3d 339, 346 (9th Cir. 1996). Here, however, Plaintiff’s wrongful termination and retaliation claims both “specifically” arise *solely* under the law and public policy of the United States concerning the federal regulation of “Investigational New Drug Applications” and “Biological Products.” Complaint ¶¶ 15, 27. Indeed, Plaintiff predicates both claims *exclusively* upon his alleged “disclosure” of a purported “violation” of the federal regulations governing areas over which the federal government maintains exclusive jurisdiction. *Id.*; 21 C.F.R. § 312.2. Plaintiff advances *no alternative and independent theories*—no congruent state law or regulation, or local ordinance—in support of his claims.

17. Title 21’s purpose, as established by longstanding precedent, is to institute a national “scheme of drug regulation [ ] designed to ensure the nation’s drug supply is safe and effective.” *See*

1 *United States v. Dotterweich*, 320 U.S. 277, 280 (1943). As the Supreme Court has repeatedly  
 2 recognized, Congress has determined that the best way to meet the Food and Drug Administration’s  
 3 goals is to prohibit the sale of drugs before they are rigorously tested and subjected to the careful  
 4 scrutiny of federal regulators. *Weinberg v. Hynson, Westcott and Dunning*, 412 U.S. 609 at 623  
 5 (1973); *see also* 21 C.F.R. §§ 312.2, 312, and 600. The FDCA (and specifically Title 21) accordingly  
 6 delineate the strict requirements governing the clinical investigation of pharmaceutical products that  
 7 seek to be lawfully marketed in the United States. *See* 21 C.F.R. § 312.2(b). In other words,  
 8 California does not regulate, control, or police the research, development, or distribution of  
 9 pharmacological products. The federal government does.

10 18. The federal government accordingly has an established and considerable public  
 11 policy interest in the interpretation and enforcement of the FDCA. Resolution of a federal question  
 12 as to the scope of 21 C.F.R. §§ 312 and 600 is therefore “necessary” for Plaintiff to prevail.

### 13 **B. Substantiality**

14 19. To determine if a federal question is “substantial,” “it is not enough that the federal  
 15 issue be significant to the particular parties in the immediate suit,” but rather depends on “the  
 16 importance of the issue to the federal system as a whole.” *Gunn v. Minton*, 568 U.S. at 258.

17 20. Cases in which the Court has found a “substantial federal interest” are those which  
 18 implicate the federal government’s powers or its ability to carry out some sort of nationwide  
 19 program; often, the interest of having federal courts adjudicate the issue strengthens the claim of a  
 20 substantial federal interest. *Grable & Sons Metal Prods., Inc. v. Darue Eng’g & Mfg.*, 545 U.S. 308  
 21 (2005). In *Grable*, the Supreme Court found federal jurisdiction over a state law quiet title action, to  
 22 which the Federal Government was not a party, alleging that the seizure and sale of a property were  
 23 invalid because the IRS had failed to comply with federal notice requirements. *Id.* at 310-311. The  
 24 *Grable* Court held that the action concerned “an important issue of federal law that sensibly belongs  
 25 in a federal court” because it implicated “the ability of the IRS to satisfy its claims from the property  
 26 of delinquents,” so the federal government “has a direct interest in the availability of a federal forum  
 27 to vindicate its own administrative action.” *Id.* at 315.

21. A similar federal interest exists here. Just as the plaintiff's claims in *Garble* implicated the federal government's interests in collecting delinquent taxes, here Plaintiff's claims necessarily implicate the federal government's substantial interest in nationally regulating biopharmaceutical research, development, and distribution, as articulated by *Dotterweich*, *Weinberg*, and their progeny.

22. Federal regulation of biopharmacology necessarily compels hearing Plaintiff's claim in this Court. Relegating to an individual state court the authority to interpret the FDCA, and by extension to interpret the FDCA's regulations in connection with an individual biosciences company's research activities, would contravene the fundamental purpose of *federally* regulating the biopharmaceutical industry.

### C. Supplemental Jurisdiction

23. Additionally, pursuant to 28 U.S.C. § 1367(a), this Court has supplemental jurisdiction over state law claims that form part of the same case or controversy under Article III. State and federal claims form part of the same constitutional "case" when they derive from a common nucleus of operative fact" and are such that "considered without regard to their federal or state character ... [Plaintiff] would ordinarily be expected to try them all in one judicial proceeding." *United Mine Workers of Am. v. Gibbs*, 383 U.S. 715, 725 (1966) (holding the federal court has discretion to exercise pendent jurisdiction over the state claim based upon state law if the state-created claim and the federal claim derive from a common nucleus of operative fact, and are such that a plaintiff would ordinarily be expected to try them all in one judicial proceeding); 28 U.S.C. § 1367(a) ("in any civil action of which the district courts have original jurisdiction, the district courts shall have supplemental jurisdiction over all other claims that are so related to claims in the action within such original jurisdiction that they form part of the same case or controversy under Article III of the United States Constitution"); *see also Baer v. First Options of Chicago, Inc.*, 72 F.3d 1294, 1299 (7th Cir. 1995) ("The statute extends the jurisdiction of the federal district court to all claims sufficiently related to the claim on which its original jurisdiction is based to be part of the same case or controversy within the meaning of Article III of the Constitution ... A loose factual connection



1 between the claims is generally sufficient.”).

2 24. To the extent that resolution of Plaintiff’s causes of action will depend upon this  
3 Court’s analysis of California law, this Court has supplemental jurisdiction over Plaintiff’s state law  
4 claims as they arise out of and are related to the same underlying allegations on which Plaintiff bases  
5 his claim that Xyphos’ conduct violated 28 C.F.R. §§ 312 and 600. Plaintiff would be expected to  
6 try all these issues in the same judicial proceeding. Stated another way: because both of Plaintiff’s  
7 claims are premised upon his allegation that Xyphos violated 28 C.F.R. §§ 312 and 600, both  
8 implicate the same jurisdictional concerns.

9 **VI. CONCLUSION**

10 25. Because jurisdiction is proper under 28 U.S.C. § 1331 (Federal Question), Xyphos  
11 respectfully requests that this Court exercise its removal jurisdiction over this action.

12 26. If this Court has a question regarding the propriety of this Notice of Removal, Xyphos  
13 requests that it issue an Order to Show Cause, so that it may have an opportunity to address such  
14 questions.

15 DATED: May 12, 2022

OGLETREE, DEAKINS, NASH, SMOAK &  
STEWART, P.C.

18 By:   
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